UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D412522; **FILE SYMBOL No.**: 83520-EO; **PRODUCT NAME**: Asulam 36.2 SL Herbicide; **DECISION No.**: 477708; **PC Code(s)**: 106902; **ACTION CODE**: R333; **FOOD Use**: Yes

DATE OUT: January 18, 2014

SUBJECT: End Use Product Chemistry Review
Product Name: Asulam 36.2 SL Herbicide

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

02-18-14

TO: Dianne Morgan / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

Company Name: Tacoma AG LLC
Formulation Type: Herbicide (SL, Soluble Concentrate)

INTRODUCTION:

The registrant Tacoma Ag, LLC has submitted an application to register a new end use product Asulam 36.2 SL Herbicide containing sodium salt of Asulam as the active ingredient with product label claim of 36.2%. The active ingredient in the proposed product is obtained by [redacted] The Asulam TGAI was manufactured by [redacted]
The registrant has submitted the product chemistry data for the proposed end use product and as well as group A & group B data for the unregistered Asulam with MRID nos. 491050-01 to 491050-04. The registrant has submitted a CSF for basic formulation (dated March 22, 2013) for the proposed product.

TRB has been asked to review the group A & B product chemistry data submitted for the unregistered source of the AI (Asulam) and for the proposed end use product.

Note: The product chemistry report for the unregistered Asulam is given on Page 6 of this report.

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: D412522; **FILE SYMBOL No.**: 83520-EO; **PRODUCT NAME**: Asulam 36.2 SL Herbicide; **DECISION No.**: 477708; **PC Code(s)**: 106902; **ACTION CODE**: R333; **FOOD Use**: Yes

End-use product Report

SUMMARY OF FINDINGS:

1, Name of Active Ingredient(s): Sodium salt of Asulam (36.2%)

2. Has the registrant claimed substantial similarity to a registered product?

[ ] Yes; [X] No; [ ] NA; if yes give the registration number of the cited product.

EPA Reg. No:

3. All of the source materials of the active ingredient are derived from registered sources
[ ] Yes; [X] No

Note: The registrant has used unregistered source for the active ingredient Asulam and to support it, the registrant has submitted product chemistry data has been submitted.

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed Label uses: [X] Yes; [ ] No; [ ] NA.

5. Confidential Statement of Formula(s):

[X] Proposed Basic - Dated: 03-22-2013; Re-submitted - Dated:

[ ] Proposed Alternate CSF – Dated: ; Re-submitted – Dated:

Alternate CSF(s) complies with 40CFR§152.43: [ ] Yes; [ ] No; [X] NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product Product label (PR Notice 91-2).

[X] Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other Ingredients)

[ ] Yes; [X] No; if not, explain below

Metallic equivalent:	[ ] Yes [X] NA;
Soluble arsenic:	[ ] Yes [X] NA
Isomeric ratios:	[ ] Yes [X] NA;
Acid Equivalent:	[X] Yes [ ] NA; Asulam equivalent = 33.1%

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: [ ] Yes [X] No [ ] NA
Methanol at > 4%: [ ] Yes [X] No [ ] NA
Sodium nitrate/Sodium nitrite [ ] Yes [X] No [ ]

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
[ ] Yes [X] No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
[ ] Yes; [ ] No; [X] NA; if not, explain below

d. Label requires an additional Storage and Disposal statement: [ ] Yes [X] No; if yes explain below:

DP BARCODE No.: D412522; **FILE SYMBOL No.**: 83520-EO; **PRODUCT NAME**: Asulam 36.2 SL Herbicide; **DECISION No.**: 477708; **PC Code(s)**: 106902; **ACTION CODE**: R333; **FOOD Use**: Yes

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	491050-01
830.1600	Description of materials used to produce the product		X		A	491050-01
830.1650	Description of formulation process		X		A	491050-01
830.1670	Discussion on the formation of impurities		X		A	491050-01
830.1700	Preliminary analysis		X		A	491050-01
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Basic CSF (03-22-13)
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X			491050-01

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Solid (powder)	A	491050-04
830.6314	Oxidation/reduction	Compatible with water, ammonium phosphate, 0.1M potassium permanganate & kerosene. Not compatible with Fe powder.	A	491050-04
830.6315	Flammability	No flash point up to the B.P. of 103°C	A	491050-04
830.6316	Explodability	Does not have explosive properties		491050-04
830.6317	Accelerated Storage stability	Stable for 2 weeks at 54°C		491050-04
830.6320	Corrosion characteristics	Will be submitted later		491050-04
830.7000	pH	5.76 @ 23°C (1% aqueous solution)	A	491050-04
830.7100	Viscosity	3.3mm2 at 20°C & 1.82mm2/s at 40°C	U	491050-04
830.7300	Bulk Density	1.178 g/ml (9.82 lbs/gal) @ 20°C	A	491050-04

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The proposed CSF for basic (dated 03-22-2013) is acceptable. The product may contain one carried over impurity from the technical Asulum.

2. The data submitted corresponding to guidelines 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) are acceptable.

3. The product chemistry data submitted corresponding to guideline 830 series group B data (physical-chemical properties) are acceptable, including accelerated storage stability study. The data given for the guideline 830.7100 needs further explanation, See Item #4.

4. The registrant must clarify data provided for the guideline 830.7100 (viscosity). The registrant has indicated in the Physical State (830.6303) of the product to be Solid (powder). However given data for viscosity as 3.3 mm2/s at 20°C and 1.82mm2/s at 40°C.

5. The registrant must generate one year one year storage stability & corrosion characteristics studies for the proposed product and the results must be submitted to the Agency for evaluation.

Product ingredient source information may be entitled to confidential treatment

[redacted]

SUMMARY OF FINDINGS & CONCLUSIONS:

TRB has evaluated the product chemistry data submitted corresponding to guideline 830 series group A & B to support the unregistered active Asulam and has concluded:

1. 830.1600 (description of materials used to produce the product):
   (MRID No. 491050-01)

The information submitted on the starting materials used to produce the Asulam TGAI is acceptable. The registrant has provided the information regarding the supplier and purity & composition of each of the starting materials.

2. 830.1620 (description of production process)
   (MRID No. 491050-01)

The data submitted is acceptable. The registrant has provided the details of the production process. The production process for this TGAI involves three steps. Details of the each step have been provided.

3. 830.1700 (preliminary analysis)
   (MRID No. 491050-02)

The data submitted is acceptable. The registrant has provided the details of the analytical method used to identify & quantify the active ingredient and the impurities in the in TGAI/MUP. The registrant has provided details of the analytical methods used for the active ingredient and each of the carried over impurities present in the technical Asulam. The study was conducted under GLP in compliance to 40CFR§160. The registrant has provided the validated analytical method used to identify & quantify the active ingredient Asulam technical and the carried over impurities.

4. 830 series group B (physical-chemical properties)

The data submitted is acceptable. The registrant has submitted physical-chemical properties of the unregistered diethanolamine salt of glyphosate and the technical glyphosate acid.

5. 830.1670 (discussion of the formation of impurities)
   (MRID No. 491050-01)

The data submitted for the guideline is acceptable. The registrant has described the origin of the carried over impurities from Asulam technical present in the TGAI/MUP diethanolamine salt of glyphosate.

DP BARCODE No.: D412522; **FILE SYMBOL No.**: 83520-EO; **PRODUCT NAME**: Asulam 36.2 SL Herbicide; **DECISION No.**: 477708; **PC Code(s)**: 106902; **ACTION CODE**: R333; **FOOD Use**: Yes

6. 830.1750 (certified limits)
(MRID No. 491050-01)

The data submitted for the guideline is acceptable. The registrant has proposed the standard certified limits for the active ingredient and the certified limits for the impurities are based on the five batch analysis.

830.1550: Product identity & Composition:

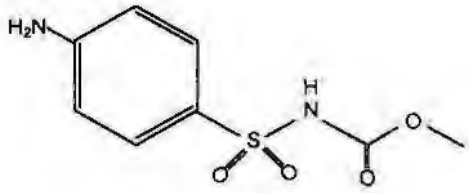
Common name: Asulam

Chemical name: Methyl-[(4-aminophenyl)sulfonyl]carbamate]

Molecular formula: $C_8H_{10}N_2O_4S$

Molecular weight: 230.2

Structural formula:



Asulam

AI in End use product

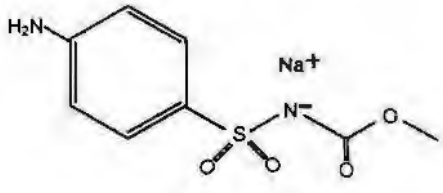
Common name: Sodium salt of Asulam

Chemical name: Sodium salt of Methyl-[(4-aminophenyl)sulfonyl]carbamate]

Molecular formula: $C_8H_9N_2NaO_4S$

Molecular weight: 252.2

Structural formula:



Asulam-Sodium

830 Series Group B (physical-chemical properties) for Asulam TGAI/MUP
(MRID No. 491050-03)

Test	Test conditions	Result
Color	Room Temperature*	Light ivory
Physical State	Room Temperature*	Solid Powder
Odor	Room Temperature*	Odorless
Stability	Room Temperature (25 ± 2 °C)	Asulam was considered to be stable in terms of active ingredient content when exposed to iron, aluminium, iron (II) acetate and aluminium acetate for 14 days at room temperature.
	54 ± 2 °C	Asulam was considered to be stable in terms of active ingredient content when exposed to iron, aluminium, iron (II) acetate and aluminium acetate for 14 days at 54 ± 2 °C.
	54 ± 2 °C (Accelerated Storage Stability)	The test item is thermally stable for 14 days at 54 ± 2 °C.

Test	Test conditions	Result	
Oxidation/Reduction	Room Temperature*	The test item did not react vehemently with iron powder, water, $NH_4H_2PO_4$, kerosene, but not compatible with $KMnO_4$	
pH	Room Temperature*	3.24	
UV-Vis	pH 4.57	log ε (260 nm)= 4.25	
	pH 1.14	log ε (217 nm, 266 nm, 271 nm)= 4.13, 3.79, 3.78	
	pH 12.71	log ε (213 nm, 256 nm)= 4.71, 4.28	
Melting Point	-	140.1-141.8 °C	
Density	20.0 ± 0.1 °C	1.25 g/mL	
Dissociation Constant	Room Temperature*	pKa = 4.29	
Partition Coefficient	25.0 °C	Log Pow = 0.12	
Solubility	20.0 ± 0.5 °C	water	4.72 g/L
		methanol	241.90 g/L
		n-octanol	2.31 g/L
		n-hexane	<4.41 mg/L

* Note: Room temperature was recorded at the day of experiments, and presented in chapter 4.

Pages 9-12 Manufacturing process information may be entitled to confidential treatment

Pages 13-15 Confidential Statement of Formula may be entitled to confidential treatment